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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/954,759	09/18/2001	John K. Morris	MED-04703/29	8880

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John G. Posa
GIFFORD, KRASS, GROH, SPRINKLE,
ANDERSON & CITKOWSKI, P.C.
280 N. Old Woodward Ave., Suite 400
Birmingham, MI 48009

EXAMINER

DEMILLE, DANTON D

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,759	Applicant(s) MORRIS ET AL.	
	Examiner Danton DeMille	Art Unit 3764	<i>CA</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,24-37 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,24-37 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claims 21, 24-37, 45-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6290662.** Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to leave out the details of the pressure sensor and program the electrical circuitry to perform any desired method of therapy desired. Claim 21 is broader than those of the patent and therefore is anticipated by the patent claims. Every limitation in claim 21 has already been recited in the patent claims. There is no unobviousness to leave out limitations so as to not be so limited. If a claimed invention in the application is obvious over a claimed invention in the patent, there would be an unjustified extension of the patent and an obvious-type double patenting rejection is proper. See MPEP 804.

Claim Rejections - 35 USC § 112

5. **Claims 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

6. There is no clear antecedent basis for “the substantially inelastic outer shell”. Claim 36 appears to be redundant. Claim 37 appears to go outside the scope of claim 21. Fabric is not rigid.

Claim Rejections - 35 USC § 103

7. **Claims 21, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson 5,496,262 in view of Taheri ‘458.**

8. Johnson teaches rigid shells 7a and 7b for wearing around a human leg. An inflatable bladder 6 and 6b is supported between the inner wall of the outer shell and the portion of the human limb. Johnson teaches an air compressor pump 1 and a controller 1a operative to inflate the bladder on a periodic basis to create a level of compression. Johnson appears silent with regard to the power source. It would appear obvious to use any conventional power source such as an electrical outlet or batteries. The air pump of Johnson is a relatively small air pump of the type used to aerate aquariums. Johnson teaches column 2, lines 56-58, “The present invention remedies this problem by providing graduated pulsating compression to the affected limb whether the patient is mobile or immobile.” For the patient to be mobile while using the device it would have to be portable. This would appear to require the device to be battery operated.

9. Taheri also teaches an intermittent compression leg brace with the details of the power system wherein “The compressor 66 is a small portable battery operated pump, and the

electronics 70, 71 and 72 consist of a microcircuit which has very small volume and weight. The foregoing features thus enhance the portability of the device.”

10. It would have been obvious to one of ordinary skill in the art to modify Johnson and use a portable control system such as taught by Taheri so that the Johnson device has a portable control system to provide the mobility needed.

11. **Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 21 above, and further in view of Zheng et al. ‘226.**

12. Taheri uses a program memory 72 for controlling the inflation operation of the bladders. The inflatable bladders are inflated as desired provided by the program memory. The only difference between the dependent claims and Taheri is the functional intended use parameters of operation. The dependent claims merely recite operating the device by varying the levels pressure or varying the rate of cycling, for example. These operational parameters are conventional variables well within the realm of the artisan of ordinary skill. There is no unobviousness to vary any one of these operational parameters dependent on practical considerations of intended use. Not every patient requires the same intensity or length of application. There appears to be no unobviousness to modify the programming to accommodate a specific patient or specific type of treatment. Clearly the program memory of Taheri is capable of inflation of the bladders as desired. It is only a matter of storing the desired steps in the program memory. The specific timing and pressures are well known variables that the registered practitioner varies all of the time. There is no criticality to any one specific method.

13. Zheng teaches that the cycle of inflation and deflation “may be repeated or varied according to the change of the time interval between square waves (55) and (56) as well as

between square wave (58) and the first square wave (51') in the next cycle." (column 10, lines 32-37) This teaches that the time interval after deflation of all cells (58) and before inflation of the next cycle (51') can be varied rather than have the same time period repeated every time. It would have been obvious to one of ordinary skill in the art to further modify Johnson to vary the rate of cycling between compression and decompression as a function of time as taught by Zheng including increasing or reducing the cycle rate dependent on the type of therapy desired or condition of a particular patient.

14. Regarding claims 25-27, 39-41, reducing the rate to be one cycle every several minutes or several hours is well within the realm of the artisan of ordinary skill through routine experimentation for a particular patient or finding the optimum results for a particular therapy and over the course of several days.

15. Regarding claims 28 and 42, Zheng teaches the cycle may be repeated or varied. Providing an automated means in which to be able to switch between the two functions would have been an obvious provision in Taheri.

16. **Claims 29, 30, 32, 33, 34, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 21 above, and further in view of Lina '237.**

17. Lina includes pressure sensors 40(A) to assure pressure within the bladder reaches the desired maximum pressure. It would have been obvious to one of ordinary skill in the art to further modify Johnson to include a pressure sensor as taught by Lina to make sure the bladder reaches the desired maximum level.

18. It would appear to be well within the realm of the artisan of ordinary skill to find the

optimum level of compression, timing, rate of cycling or any operational parameter to achieve the best treatment for a particular therapy for a particular patient.

19. Lina teaches varying the level of compression as a function of time in column 20, lines 5-13, "Upon system start-up, the initial pressure in the first inflate mode is low because the inflate solenoid valve is only briefly energized (25 milliseconds in the preferred embodiment). During each subsequent inflate mode, the inflate solenoid valve energization time increases by 25 milliseconds until that energization time reaches the operator selected or default pressure level, and the foot pump is delivering the desired pressure to the patient's foot." Therefore the pressure level in each subsequent cycle is being increased resulting in a ramping feature to reduce patient alarm by allowing the patient to gradually become acclimated to the pressure pulses. It would have been obvious to one of ordinary skill in the art to further modify Taheri to operate the controller to vary the level of compression as a function of time as taught by Lina to gradually increase the pressure so that the patient can become acclimated to the pressure pulses.

20. Regarding claims 23, 48, with each increase of inflate time this would then vary the onset of the decompression. Each iteration of inflation increases the inflation period 25 milliseconds therefore the onset of the decompression would also be pushed back 25 milliseconds. This would appear to comprehend claims 23, 48.

21. Claims 31, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 21 above, and further in view of Vinmont.

22. Vinmont teaches the convention of using the inflatable bladder system inside a cast. There is no unobviousness to the intended use of the system. Vinmont exemplifies another conventional alternative rigid outer shell formation. Johnson comprehends any rigid shell for the

outer shell. A cast is just such a shell. It would have been obvious to one of ordinary skill in the art to further modify Johnson for use in another equivalent alternative rigid shell as a cast as taught by Vinmont since the art of improving cardiocephal venous flow applies to people in casts who are likewise ambulatory as well as taught by Vinmont.

23. **Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 21 above, and further in view of Corcoran.** Corcoran teaches the convention of stimulating the hand as well as the foot. It would have been obvious to one of ordinary skill in the art to further modify Taheri to use the device for the hand as well as the foot as taught by Corcoran for those people who need to stimulate circulation of those limb extremities.

24. **Claims 45, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri '458 in view of Arkans '961 and Lina '237.**

25. Taheri teaches a flexible fabric outer shell, an inflatable/deflatable bladder A-D supported between the inner wall of the outer shell and the human limb and column 4, lines 49-53, teach "[t]he compressor 66 is a small portable battery operated pump, and the electronics 70, 71 and 72 consist of a microcircuit which has very small volume and weight. The foregoing features thus enhance the portability of the device." Clearly Taheri teaches all of the structure recited but appears silent with regard to whether or not the fabric outer shell is inelastic or not. Column 3, lines 35-38 state, "when the bladders are inflated, they will bulge inwardly toward the adjacent soft tissue to provide good pressure against the deep veins." In order to achieve the best result of directing the expansion of the bladders inwardly toward the adjacent soft tissue to provide good pressure against the deep veins it is well know to provide some degree of hardness or resistance

to expansion of the outer layer to direct most of the expansion inwardly. A lot of the force of expansion would be lost if the outer layer is also elastic allowing the bladder to expand outwardly. This would not be most efficient and would be counter productive contrary to the teaching of Taheri.

26. Arkans '961 exemplifies the art of inflatable bladders having an "outer cover sheet 36 may comprise a relatively inelastic fabric" (column 2, lines 55-56). "The inelastic cover sheet 36 of the placed sleeve restricts the size of the inflated chambers, and greatly enhances the compressive action of the chambers to permit lower fluid volumes during the compression cycles." (column 5, lines 29-33).

27. Lina teaches varying the level of compression as a function of time as noted above.

28. It would have been obvious to one of ordinary skill in the art to modify the cover of Taheri to be inelastic as taught by Arkans to greatly enhance the compressive action of the chambers by limiting the expansion of the bladder inwardly against the body and to vary the level of compression as a function of time as taught by Lina to tailor the method of operation to the particular needs of a patient and type of therapy.

29. **Claims 46-47, 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 45 above, and further in view of Zheng et al. '226.**

30. As noted above there is no unobviousness to find the optimum operating parameters for a particular type of treatment for a particular type of patient. The specific timing and pressures are well known variables that the registered practitioner varies all of the time. There is no criticality to the methods claimed. The computer memory of Taheri is capable of holding any program desired. Zheng teaches that the cycle of inflation and deflation "may be repeated or varied

according to the change of the time interval between square waves (55) and (56) as well as between square wave (58) and the first square wave (51') in the next cycle." (column 10, lines 32-37) This teaches that the time interval after deflation of all cells (58) and before inflation of the next cycle (51') can be varied rather than have the same time period repeated every time. It would have been obvious to one of ordinary skill in the art to further modify Taheri to vary the rate of cycling between compression and decompression as a function of time as taught by Zheng including increasing or reducing the cycle rate dependent on the type of therapy desired or condition of a particular patient.

31. Regarding claims 47, 50, Zheng teaches the cycle may be repeated or varied. Providing an automated means in which to be able to switch between the two functions would have been an obvious provision in Taheri.

Response to Arguments

32. Applicant's arguments with respect to claims 21, 24-37 and 45-50 have been considered but are moot in view of the new ground(s) of rejection.

33. Applicant argues that the teaching of Lina "has no bearing on the instant invention or claims". It is not clear how applicant can disregard the teaching of Lina. Applicant claims varying the level of compression as a function of time. Lina teaches a method of slowly increasing the maximum level of pressure during each cycle so that as to ease the patient into the pressure therapy program. The operator does not want to shock the patient by applying full pressure all at once but rather ease the patient into the regimen. This teaches what applicant is claiming and therefore very relevant.


34. Zheng as well as Lina teach that it is well within the realm of the artisan of ordinary skill to vary the operational parameters of inflating the cells within the limb brace to effect proper blood circulation within the limb. As noted above these references teach applicant's structure. The only difference is how you operate the device. Applicant's claimed operational methods merely vary conventional parameters. Such are well know variables to one of ordinary skill in the art to vary dependent on the specific type of conditions of the patient.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

36. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ddd
8 October, 2004
☎ (703) 308-3713
Fax: (703) 872-9306
Starting 03 November 2004: ☎ (571) 272-4974
danton.demille@uspto.gov


Danton DeMille
Primary Examiner
Art Unit 3764